

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

TWINSTRAND BIOSCIENCES, INC., &  
UNIVERSITY OF WASHINGTON,

*Plaintiffs,*

v.

GUARDANT HEALTH, INC.,

*Defendant.*

C.A. No. 21-1126-GBW-SRF

**STATUS REPORT**

Pursuant to the Court's September 14, 2022 Order, the parties hereby update the Court on their efforts to narrow claim construction disputes and to identify the terms that remain in dispute that will be addressed in the Joint Claim Construction Brief and at the December 6, 2022 *Markman* hearing.

Plaintiffs and Guardant have each asserted 4 patents in the above-captioned action. Since the submission of the Joint Claim Construction Chart (D.I. 84) on July 1, 2022, the parties have agreed to the constructions of 8 terms, listed in Appendix A. Further, Plaintiffs have dropped 18 asserted claims<sup>1</sup>, thereby mooted the need to construe 4 terms listed in Appendix B.

Only 12 terms remain in dispute, and those are listed in Appendix C.

---

<sup>1</sup> Plaintiffs no longer assert the following claims: Claims 2, 8, 10, 17, and 20 of U.S. Patent No. 10,287,631; Claims 3, 14, 16, and 27 of U.S. Patent No. 10,689,699; Claims 10, 20, 21, and 24 of U.S. Patent No. 10,752,951; and Claims 10, 11, 14, 26, and 29 of U.S. Patent No. 10,760,127.

YOUNG CONAWAY STARGATT  
& TAYLOR, LLP

/s/ Samantha G. Wilson

Adam W. Poff (No. 3990)  
Samantha G. Wilson (No. 5816)  
Rodney Square  
1000 North King Street  
Wilmington, DE 19801  
(302) 571-6600  
apoff@ycst.com  
swilson@ycst.com

*Of Counsel:*

Byron Pickard  
R. Wilson Powers III, Ph.D.  
Chandrika Vira  
Anna G. Phillips  
Matthew M. Zuziak  
STERNE, KESSLER, GOLDSTEIN  
& FOX, P.L.L.C.  
1100 New York Avenue, NW  
Washington, DC 20005  
(202) 371-2600  
bpickard@sternekessler.com  
tpowers@sternekessler.com  
cvira@sternekessler.com  
aphillips@sternekessler.com  
mzuziak@sternekessler.com

*Attorneys for Plaintiffs TwinStrand Biosciences,  
Inc. and University of Washington*

DLA PIPER LLP (US)

/s/ Jeff Castellano

Brian A. Biggs (No. 5591)  
Erin E. Larson (No. 6616)  
Jeff Castellano (No. 4837)  
1201 North Market Street, Suite 2100  
Wilmington, DE 19801  
(302) 468-5700  
brian.biggs@us.dlapiper.com  
erin.larson@us.dlapiper.com  
jeff.castellano@us.dlapiper.com

*Of Counsel:*

Mark D. Fowler  
Susan Krumplitsch  
Monica De Lazzari  
DLA PIPER LLP (US)  
2000 University Avenue  
East Palo Alto, CA 94303  
(650) 833-2048  
mark.fowler@us.dlapiper.com  
susan.krumplitsch@us.dlapiper.com  
monica.delazzari@us.dlapiper.com

Michael A. Sitzman  
DLA PIPER LLP (US)  
555 Mission Street  
Suite 2400  
San Francisco, CA 94105  
(415) 615-6175  
michael.sitzman@us.dlapiper.com

Ellen Scordino  
Kristin Beale  
DLA PIPER LLP (US)  
33 Arch Street  
26th Floor  
Boston, MA 02110  
(617) 406-6085  
ellen.scordino@us.dlapiper.com  
kristin.beale@us.dlapiper.com

Dated: September 16, 2022

*Attorneys for Defendant Guardant Health, Inc.*

## Appendix A

Agreed-Upon Constructions for Terms in Plaintiffs' Asserted Patents		
Claim Term	Patent, Claim	Agreed Upon Construction
uniquely labels	'631 patent, claim 1	Plain and ordinary meaning
quantifying at least two of (i) said paired sequence reads, (ii) said unpaired sequence reads, (iii) read depth of said paired sequence reads, and (iv) read depth of said unpaired sequence reads	'951 patent, claim 1	Plain and ordinary meaning
partially single-stranded adapters	'127 patent, claim 22	Plain and ordinary meaning with the understanding that the term can include both Y-shaped and U-shaped adaptors
partially complementary, asymmetrical double-stranded adapter-DNA molecules	'127 patent, claim 1	Plain and ordinary meaning with the understanding that the term can include both Y-shaped and U-shaped adaptors
other fragment regions	'631 patent, claim 18	Plain and ordinary meaning
circulating DNA molecule(s)	'699 patent, claims 1, 8, 9, 12, 17–20, 24, 25	DNA molecules that circulate within the circulatory system, which can include cell-free DNA and cellular DNA

double-stranded circulating nucleic molecules	'951 patent, claims 11, 12, 15, 16, 18	Double-stranded nucleic acid molecules that circulate within the circulatory system, which can include cell-free DNA and cellular DNA
---	--	---

Agreed-Upon Constructions for Terms in Guardant's Asserted Patents		
Claim Term	Patent, Claim	Agreed Upon Construction
"cell-free deoxyribonucleic acid (cfDNA)"	'063 patent, claims 15 and 24  '858 patent, claims 1, 3, and 5  '221 patent, claims 1–5  '306 patent, claims 17, 19, and 20	"DNA that exist(s) outside of a cell while in the body, including in blood, plasma, serum, urine, saliva, mucosal excretions, sputum, stool, cerebral spinal fluid, or tears."
"a family of the families"	'063 patent, claim 17	"a single family from the plurality of families"

## **Appendix B**

Because Plaintiffs are no longer asserting certain patent claims, the need to construe the following terms has been mooted:

- “non-unique polynucleotide barcode”;
- “non-uniquely tagged double stranded adapter-DNA molecules”;
- “substantially identifiable”; and
- “sufficiently unique...substantially differentiated.”

## Appendix C

Terms Requiring Construction in Plaintiffs' Asserted Patents			
Claim Term	Patent, Claim	Plaintiffs' Proposed Construction	Defendant's Proposed Construction
degenerate ... sequence(s)	'631 patent, claims 1, 12, 13, 15;  '951 patent, claim 23;  '127 patent, claim 13	a nucleotide sequence that is known or unknown in which every nucleotide position is unrestricted in its nucleotide variability	[single molecule identifier (SMI) / oligonucleotide] sequence in which all of the nucleotides have been randomly generated
semi-degenerate ... sequence(s)	'631 patent, claims 1, 12, 13, 15;  '951 patent, claim 23;  '127 patent, claim 13	a nucleotide sequence that is known or unknown in which at least one nucleotide position is fixed or restricted in its nucleotide variability	[single molecule identifier (SMI) / oligonucleotide] sequence in which some of the nucleotides have been randomly generated
fragment ends	'631 patent, claim 1	Plain and ordinary meaning	Each fragment end is made up of fewer nucleotides than the entire fragment at the terminal end of the fragment after shearing and trimming
non-uniquely tagged parent polynucleotide(s)	'699 patent, claims 1, 18;	a population of parent polynucleotide molecules affixed to polynucleotide barcodes, wherein the same polynucleotide barcode sequence is affixed to multiple parent polynucleotide	Indefinite

		molecules in the [population/sample], and wherein the polynucleotide barcode sequence serves as a molecular identifier only when combined with other information from the tagged parent polynucleotide molecule	
non-unique tag	'951 patent, claim 25	a tag that is affixed to a parent polynucleotide molecule and having a nucleotide sequence, wherein the same tag nucleotide sequence is affixed to multiple parent polynucleotide molecules in the sample, and wherein the tag nucleotide sequence serves as a molecular identifier only when combined with other information from the tagged parent polynucleotide molecule	Indefinite
substantially unique	'699 patent, claims 1, 20	Plain and ordinary meaning; not indefinite	Indefinite
high accuracy sequence reads	'631 patent, claims 1, 16	Plain and ordinary meaning; not indefinite	Indefinite
high accuracy consensus sequence read	'631 patent, claims 1, 4, 7, 16, 23	Plain and ordinary meaning; not indefinite	Indefinite
fragment features	'631 patent, claim 16, 18	Plain and ordinary meaning; not indefinite	Indefinite



DNA fragment-specific information	'127 patent, claim 22	Plain and ordinary meaning; not indefinite	Indefinite
-----------------------------------	-----------------------	--	------------

Terms Requiring Construction in Guardant's Asserted Patents			
Claim Term	Patent, Claim	Plaintiffs' Proposed Construction	Defendant's Proposed Construction
comprises between 1 nanogram (ng) and 100 ng of cfDNA molecules	'221 patent, claim 3  '306 patent, claim 19	1 ng or greater of cfDNA molecules	Plain and ordinary meaning
a subject having cancer	'221 patent, claim 2	a subject known to currently have cancer	Plain and ordinary meaning

29734445.1